IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2848
THIS DOCUMENT RELATES TO:	:	
SANDRA BILLECI & DENNIS BILLECI	:	CIVIL ACTION NO. 17-486
v.	:	
MERCK & CO., INC., AND MERCK SHARP & DOHME CORP.	:	

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 471

Bartle, J. March 16, 2023

This action is part of a multidistrict litigation in which plaintiffs allege that they suffered injuries as a result of being inoculated by defendants' vaccine against shingles, Zostavax. Before the court is the motion of defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (now Merck Sharp & Dohme LLC) in this specific action, Billeci, et al. v. Merck & Co., Inc., et al., Civ. A. No. 17-486, for partial summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. Now that discovery has concluded, defendants contend that judgment should be granted in their favor as a matter of law as to plaintiff Sandra Billeci's claims for negligent failure to warn and for strict liability failure to warn.

Defendants maintain that plaintiffs have presented no evidence of an essential element of those claims.

I

Plaintiff Sandra Billeci received a dose of the Zostavax vaccine in California in 2014. Shortly thereafter, she developed a condition she described as a "tingling" or "pinprickly" sensation. She was later diagnosed with peripheral neuropathy and allodynia, which are both serious conditions that affect one's nervous system.

Billeci was prescribed Zostavax by her physician, Irena Rozen. Rozen testified in a deposition about the types of side effects that she would like to know about before deciding to prescribe a particular medication:

> Q. How about this, I'll summarize it. So whenever you are prescribing a medication including Zostavax, would you want to know about all the potential side effects that could occur?
>
> A. No, I just want to know about most common ones.
>
> Q. The most common ones?
>
> A. Right.
>
> Q. Okay. And so you would agree that if there is a -- if there are potential side effects that are common out there, you would want to see that in the label?
>
> A. If they are common, yes.

Billeci alleges in this lawsuit that her inoculation with Zostavax caused her peripheral neuropathy and allodynia.

II

Summary judgment is appropriate under Rule 56 of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A factual dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A factual dispute is material if it might affect the outcome of the suit under governing law. Id. at 248. It is the nonmoving party's burden to show that there is some "evidence on which the jury could reasonably find" in its favor. Id. at 252.

III

Defendants have moved for summary judgment on the ground that Billeci cannot maintain her failure-to-warn claims based on Rozen's testimony or any other record evidence. The parties agree that California law applies to Billeci's claims. California law imposes strict liability on drug manufacturers for injuries caused by their failure to give warning of dangers that were known or scientifically knowable at the time they

manufactured and distributed the drug. Carlin v. Superior Ct., 920 P.2d 1347, 1348-49 (Cal. 1996). A drug manufacturer may also be held liable under a theory of negligence if it "did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." Id. at 1351 (citation omitted).

Under either theory, a plaintiff must establish that the drug manufacturer's inadequate or absent warning caused him or her to suffer an injury. California law applies the learned intermediary doctrine to failure-to-warn claims over prescription drugs. Under this doctrine, "in the case of prescription drugs, the duty to warn runs to the physician, not to the patient." Id. at 1354.

To prove causation--that is, that the manufacturer's failure to warn caused the plaintiff's injury--the plaintiff must show that her physician would have acted differently had the manufacturer communicated a stronger warning. The plaintiff may make this showing with evidence that "a stronger risk warning would have altered the physician's decision to prescribe the product." Himes v. Somatics, LLC, 29 F.4th 1125, 1127 (9th Cir. 2022) (citing Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659, 660-61 (9th Cir. 2004)). Alternatively, the California Supreme Court is presently considering as a certified question

whether a plaintiff can prevail on a failure-to-warn claim by showing that "the physician would have communicated the stronger risk warnings to the plaintiff, either in their patient consent disclosures or otherwise, and a prudent person in the patient's position would have declined the treatment after receiving the stronger risk warning." Himes, 29 F.4th at 1127.

Billeci has not produced any evidence showing that Rozen, Billeci's prescribing physician, would have decided against prescribing Zostavax or would have communicated stronger risk warnings if Zostavax had included peripheral neuropathy risk warnings. Rozen testified that she would "want to know" about the risks of "common" side effects when considering whether to prescribe a medication such as Zostavax. This testimony falls short. There is no evidence that peripheral neuropathy is a "common" side effect of Zostavax. Even assuming, without deciding, that peripheral neuropathy is a "common" side effect of Zostavax, Rozen never said that knowledge of such a risk would have changed her decision to prescribe it to Billeci.[1] It is speculation that Rozen would

1. Defendants have filed an unopposed sur-reply and furnished the court with the report of the expert witness on which plaintiffs intend to rely at trial to prove specific causation. The report says nothing about the incidence of peripheral neuropathy as a side effect of Zostavax. The deadline for serving expert reports has passed.

have relayed additional risk warnings, even about "common" side effects.

For this reason, Billeci's analogy of her claims to those in Elmegreen v. Merck & Co., Inc., et al., Civ. A. No. 17-2044, is without merit. That action was part of an earlier group of bellwether plaintiffs in this multidistrict litigation who alleged that Zostavax caused them to contract shingles. The plaintiff had advanced similar failure-to-warn claims under California law. The court denied summary judgment because her prescribing physician had testified unequivocally that the physician would have conveyed stronger warnings to the plaintiff if the physician had known of the risks. See In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig., Civ. A. No. 17-2044, MDL No. 18-2848, 2021 WL 3423361, at *5 (E.D. Pa. Aug. 4, 2021). By contrast, the record here is devoid of any such evidence here.

Accordingly, the court will grant the motion of defendants for partial summary judgment as to the claims for negligent failure to warn and strict liability failure to warn of plaintiff Sandra Billeci.[2]

2. Despite having deposed Rozen twice in this action, plaintiffs now contend that the court should grant them additional time to conduct discovery necessary to respond to defendants' motion pursuant to Rule 56(d). However, that Rule requires a plaintiff to set forth "specified reasons" why it "cannot present facts essential to justify its opposition." In addition, the party must make this showing "by affidavit or declaration." Plaintiffs merely assert a desire to conduct additional discovery without specifying what additional discovery they seek to obtain or why they have not been able to obtain it thus far. Moreover, they make this request in the conclusion paragraph of their brief in opposition to defendants' motion and without reference to any affidavit or declaration. Accordingly, plaintiffs' request is not being considered.